COMPARATIVE EVALUATION OF STABILITY OF TWO DIFFERENT FORMS OF IMMEDIATELY LOADED IMPLANTS SUPPORTING A FIXED FULL ARCH PROSTHESIS. AN IN-VIVO STUDY

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In partial fulfillment for the Degree of

MASTER OF DENTAL SURGERY

BRANCH I

PROSTHODONTICS AND CROWN & BRIDGE

APRIL 2016

CERTIFICATE

This is to certify that this dissertation entitled **"COMPARATIVE EVALUATION OF STABILITY OF TWO DIFFERENT FORMS OF IMMEDIATELY LOADED IMPLANTS SUPPORTING A FIXED FULL ARCH PROSTHESIS - AN IN-VIVO STUDY"** *is a bonafide research work done by* **Dr. P.KAMALASHANKAR** *under our guidance and to our satisfaction during his post graduate study period between* **2013 – 2016.**

This dissertation is submitted to **THE TAMILNADU Dr. M.G.R. MEDICAL UNIVERSITY**, *in partial fulfillment for the Degree of* **MASTER OF DENTAL SURGERY in PROSTHODONTICS AND CROWN & BRIDGE - BRANCH I.** *It has not been submitted partially or fully for the award of any other degree or diploma.*

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Introduction

Partial or complete edentulism is a major oral health concern in a large part of the adult population and there is a need for treating a sizeable percentage of such population with prosthodontic rehabilitation. Traditional treatments comprising of removable prostheses are often inadequate in restoring full masticatory function and can negatively affect nutrition, physical appearance and self-esteem.[14,31]Osseointegrated dental implants offer effective and definitive solutions for such scenario. Dental Implants have become a milestone in dentistry and have changed the face of dentistry over the last three decades. Numerous alternative oral therapies and definitive rehabilitation procedures that could not be done with conventional techniques have been realised with the advent of osseointegrated implants. A large body of sound scientific research and decades of clinical use have verified and validated their usefulness in replacing missing teeth.[16,28,31] Clinical evidence has shown excellent long term results for osseointegrated implants with success rates above 90%.[11,14]

Dental implants were first introduced for people who were completely edentulous and who had great difficulty stabilizing or tolerating dentures, largely because of the atrophy of the alveolar bone and mucoperiosteum upon which the dentures rest. The main objective in the treatment of completely edentulous patients with osseointegrated implants is either to avoid removable complete dentures by placement of complete implant-supported fixed prosthesis or to improve retention and stability of removable complete dentures. It was well known even then that osseointegration is best in dense bone, generally in the front part of the lower jaw. It is interesting to note that the use of implants in prosthodontics was restricted to the treatment of completely edentulous mandible with a fixed prosthesis in the

earlier days. Also, the submerged protocol , two stage surgery and delayed loading were much in vogue as proposed by authors like Branemark and Alberktsson et al.[14]

Today implants are used to replace either single or multiple missing teeth apart from treating completely edentulous situations. Implants are infact proposed as the first line of treatment for many conditions which earlier were treated with either removable or fixed, tooth or tissue supported prostheses. Innovations in the design , geometry and surface characteristics of dental implants were essentially introduced to widen the scope of implant therapy to a wide range of clinical situations such as complete edentulism , long and short span partial edentulism , missing single tooth, maxillofacial prosthetics, etc. Advancements in the material science, imaging systems and prosthetic technology has also led to a phenomenal change in the way implant treatment planning and execution is carried out.

The successful outcome of any implant procedure needs a series of patient related factors (bone volume and density) and procedure dependent parameters (type of implant and surgical procedure) to be considered . Modern implants come in a variety of shapes and sizes to suit the different edentulous situations they replace and also according to the types of prosthetic teeth or superstructure to be supported by the implants. Their surfaces have been improved to enhance the osseointegration process. Instead of being smooth or machined, they are generally roughened by different manufacturing techniques which dramatically increase the surface area to which bone can attach.[22,26,41]

The successful integration of any implant is dependent on the primary stability of the implant achieved during placement and is more so with immediately loaded implants.[5,6] Primary stability is dependent on bone quality, implant design and surgical technique. Surgical techniques to improve bone quality and enhance bone density during implant

placement have been developed. Similarly , new implant designs have been proposed to achieve high stability even in poor quality bone. A combination of macro thread design to achieve high initial stability and micro roughened surface to improve bone implant contact is employed in the majority of the commercially available implants today. Modification of screw threads has been shown to increase the pullout strength of implants and influenced the insertion torque values[26,41]. New implant biomaterials are developed aiming to alter cellular performance at the bone – implant interface. Research has provided strong evidence supporting improved osseointegration , increased bone – implant contact (BIC) , increased mechanical stability and improved soft tissue health with surface treated implants. Schroeder et al observed that a rough and porous surface increases the effective surface about 12 times in relation to a smooth one generating an osteo – inductive effect and increasing the anchoring of the implant in bone.[44]

Surface texturization can be achieved through a variety of processes namely, acid etching, sand blating and associating acid treatment and particle jetting together. Also , many bioactive coated implants were proposed aiming to modify the host response at cellular level and achieve better bone integration. These include hydroxyapatite , calcium hydroxide and bisphosphonate coated implant surfaces. Recently , titanium plasma sprayed (TPS) and Resorbable blast media (RBM) treated implants are available. There were some inherent disadvantages such as incorporation of oxide particles on the implant surface , loss of coating during torquing of implants and inability to achieve homogenous roughness ,etc, with such surface treated implants. The use of low intensity laser radiation for surface treatment of implants has advantages like low contamination with chemicals and hence improved cell metabolic and functional activities.[33,44]

Attempts to decrease the treatment time with implant therapy have also been made by many authors.[30,36,43] Premature loading was considered detrimental to direct bone apposition on the implant surface and was thought to result in fibrous encapsulation. While the initial concept of submerged protocol and delayed loading was based on earlier concepts of osseointegration, continued research has led to an improved understanding of bone biology , osseointegration and host response for immediate and early loading protocols. Immediate loading is no longer considered to be risky and new clinical protocols with shortened healing periods or immediate loading have been proposed with clinical success rates comparable to the original protocol. More recent studies have illustrated that early loading of implants at a low magnitude of force may aid in early peri-implant osteogenesis.[37,43]As mentioned earlier , the main requirement to allow immediate loading of dental implant is its primary stability when inserted into the osteotomy site. The micromotion of the implant during loading in its early stages should be below 150 μm , above which fibrous encapsulation may occur[40].

In addition to the above factors, splinting of multiple implants is also expected to reduce the implant micromotion during healing stage. Immediate prosthetic loading of the implants , either functional or nonfuntional is indicated as part of treatment protocol by many clinicians. The All –on – four technique proposed by Paulo malo is one such protocol with reported success of more than 95%[36]. Immediate loading of either axially placed or tilted implants in completely edentulous jaws has now become a norm rather than exception.

Studies regarding the various factors affecting primary stability and immediate loading such as bone quality, surgical techniques and implant design and surface characteristics are available in the literature. However, many of them are either in vitro studies

done in artificial bone or cross sectional studies. While the initial mechanical stability of implants can be roughly assessed with synthetic and cadaveric bone models, the influence at cellular level due to the surface characteristics are best researched in an in vivo model which includes animal studies followed by histomorphometric analysis and human clinical trials.

Long term , Prospective human clinical trials are considered to be the gold standard in evidence based dentistry , the results of which can be extrapolated to clinical practice with more accuracy and confidence. Such clinical trials are comparatively few regarding the influence of surface treatments of implants on the primary and long term stability of implants.

Hence this clinical study was undertaken to evaluate the influence of two different surface treatments on the primary and long term clinical stability of endosteal implants supporting an immediately loaded full arch fixed prosthesis.

Aim and Objectives of the Study

AIM:

The aim of this study was to determine the difference in the primary and progressive clinical stability if any, between two types of root form endosseous implants with two distinct implant surfaces namely Acid etched surface/ Al Oxide blasted surface and Restorable blast medium (RBM) treated surface when loaded immediately with a full arch fixed prosthesis.

OBJECTIVES:

- To measure the stability of the above mentioned groups of implants immediately after insertion (Primary stability).
- To measure the stability of the above mentioned groups of implants 1 month after insertion of definitive prosthesis.
- To measure the stability of the above mentioned groups of implants 3 months after insertion of definitive prosthesis.
- To measure the stability of the above mentioned groups of implants 6 months after insertion of definitive prosthesis.
- To measure the stability of the above mentioned groups of implants 12 months after insertion of definitive prosthesis.
- To compare the difference in stability among the Al Oxide blasted / acid etched surface implants at different time intervals (at the time of insertion, 1 month, 3 months, 6 months & 12 months after insertion).
- To compare the difference in stability among the Restorable blast medium (RBM) (Calcium phosphate) treated surface implants at different time intervals (at the time of insertion , 1 month, 3 months, 6 months & 12 months after insertion).

- To compare the difference in stability between the above mentioned two different surface treated implants at different time intervals (at the time of insertion, 1 month, 3 months, 6 months & 12 months after insertion).

Review of Literature

Branemark Pl, Zarb GA, Albrektsson T et al (1985)[14] In the last three decades, implant dentistry has emerged as a fully accepted discipline in dentistry. During this period of development, its concepts and treatment modalities have undergone tremendous changes. At first, only protocols involving two-stage surgery were recognized as providing reproducible and reliable results .

Antezak-Bouckoms AA, Tulloch JF, Berkey CS (1990)[4] Several types of research designs are available including, split-mouth design, whole-mouth design, and cross-over clinical trials. The split-mouth design is a popular design in oral health research. In the most common split-mouth study, each of two treatments are randomly assigned to either the right or left halves of the dentition. The attractiveness of the design is that it removes a lot of inter-individual variability from the estimates of the treatment effect. Split-mouth design seems to be an effective type of clinical trial giving the advantages of reducing bias, obtaining definitive results, and decreasing cost.

Buser D, Weber HP, Bragger U, Balsiger C. et al(1991) [15]Proposed a single-stage surgical procedure that became acceptable.

Meredith N, Alleyne D, Cawley P. et al(1996)[34] proposed a Quantitative determination of the stability of the implant-tissue interface using resonance frequency analysis.

Meredith N, Book K, Friberg B, Jemt T, Sennerby L. et al(1997)[35] proposed a cross-sectional and longitudinal study of resonance frequency measurements on implants in the edentulous and partially dentate maxilla.

RFA is a test to assess implant stability by measuring the frequency of implant oscillation inside the bone. A transducer connected to the implant is excited by means of an electric or magnetic impulse (depending on the type of transducer used). Thus, the implant is subjected to slight lateral force that causes lateral displacement due to elastic deformation of the bone. The frequency of the registered oscillation depends on the stiffness of bone-implant attachment: the stiffer the system is, the higher the transducer's oscillation frequency will be.

There are several generations of transducers and assessment instruments. Recent generation instruments (Osstell®; Osstell AB, Gothenburg, Sweden) need no computer to complete analysis, are light, small, quick and easy to use in everyday clinic activity. Unlike previous generations, the transducer demands no calibration in 3G instruments.

Stability values are expressed in ISQ (Implant Stability Quotient) units, which range from 1 (low stability) to 100 (high stability). There is a specific transducer for each type of implant and the obtained values do not depend on the type of transducer (44).

To compare different measurements taken with the same instrument, it must be capable of reproducing highly similar values in different takes (i.e., the instrument is required to render a high degree of repeatability). Besides, the values registered by means of different Smart-Pegs must also be similar (i.e., the instrument is required a high degree of reproducibility).

Szmukler-moncler s ,salama H,reingewirtz Y et al(1998) [43]Opinions vary about the maximal acceptable interval between implant placement and loading. Some researchers use the term immediate loading only when the provisional prosthesis is placed during the same session in which surgery is performed .The delay most often observed for orderly placement of prosthesis directly after the surgical procedure ranges between several hours and 5 days. It would be tempting to use this practical framework in the definition of immediate loading. However, many studies have documented results of treatment that followed an arbitrarily determined delay of 48 to 72 hours. Furthermore, according to numerous authors, patients appear to be increasingly interested in reduced treatment time between tooth removal and delivery of the final implant-supported prosthesis, provided the level of predictability established during the previous two decades is maintained.

Misch et al(1998)[16] study has concluded that most of the immediate loaded implants are placed in anatomical sites with dense and good bone quality. The mandible has a better bone quality compared to the maxilla and this is the reason why reports are available regarding immediate loading in mandible than maxilla.

Comparatively, related number of studies has concluded the concept of immediate loading in the mandible for full arch restoration with the survival rates of 80-100% (31-33). Most of the studies published on immediate loading in the mandible have considered mainly in edentulous patients.

Van Steebergh et al (2000)[45] compared two implant systems with different surface characteristics in a split mouth randomized design and came into conclusion that no significant differences came out in concerned with probing depth or presence of plaque or

change in marginal bone level but statistically significant difference in location of marginal bone level in relation to shoulder of the implant was found in favor of self tapping TiO 2 – blasted screw shaped implants made of pure titanium in comparison with self tapping mark two implants machine surface irregularities.

Szmukler-Moncler S, Piattelli A, Favero GA, Dubruille JH et al(2000)[42] considered the application of early and immediate loading protocols in dental implantology where the waiting periods for bone healing is shortened; instead of 3 to 8 months, no more than 6 to 8 weeks was deemed necessary.

Aparicio C, Rangert B, Sennerby L., et al(2002)[5] Immediate/early loading of dental implants they believe that, to qualify as an immediately loaded implant, the definitive prosthesis must be placed on the same day .

Marjorie.k.jeffcoat et al (2003)[33] Proposed a study to compare the efficacy of the HA coated cylindrical Implant , HA coated threaded endosseous implant with that of machined threaded endosseous implant as control &all were placed as two stage procedure. The criteria of assessment was marginal bone loss not less than 2mm during 5years post loading period from base line measurement .There were no significant differences in PI ,GI probing pocket depth or gingival recession b/w groups at base line . He came in to conclusion that HA coated cylinders had the highest success rate after restoration -99% followed by HA coated threaded implants(97.9%) &titanium threaded implants-95.2%

Romanos et al,**(2003)**[37] quoted that implant stability in the immediate loading is seems to be increased due to the significant increase of the peri-implant bone density at the implant-bone interface.

Vidyasagar(2004)[46] stated that dental implant designs are influenced by overall surface area, length and thread configuration. This can gain initial stability that would reduce the threshold for the tolerated micro motion and minimize the waiting period. The design factors incorporated into the dental implants would decrease the shear forces on the interface. The design features may stimulate the bone formation and in which promotes bone healing and better load distribution . There are different types of dental implants used in dentistry.

Alexandre-Amir Aalam, etal (2005).[1] Clinical and radiographic comparison of dental implants with surface roughened by anodic oxidation(tiUnite) dual etched implants (osseotite) and machined implants and concluded that tiUnite, osseotite, and machined implants had similar short term clinical outcomes.

Wilmes et al(2006) [48]evaluated the initial stability of implant, which implies on the bone quality and the surgical technique. The primary stability could be increased with the bone quality, which would improve the osseointegration and increase the survival probability of the dental implant. Even some studies have indicated the failure rate of dental implants is high in poor-quality bone (22), and that the bone quality is higher for the mandible than for the maxilla. In addition, the survival rate is higher for dental implants placed in the mandible than for those in

the maxilla (23). It is evident that, when compared with the maxilla, the bone surrounding the implant has better volume and quality in the mandible (24).

Barone A, Rispoli L, Vozza I, Quaranta A, Covani U et al(2006)[8] In extreme, this involves insertion of an implant immediately after tooth extraction, potentially using simplified procedures such as flapless surgery, and subsequent restoration of the implant in the same session. Ultimately, this combination may not only lead to a reduction in the overall treatment time, but may also substantially decrease the associated costs. Furthermore, it has been claimed that the described approach is clearly associated with reduced surgical procedures and may more efficiently preserve the existing bone and soft tissues at the site of implantation.

Paulo Malo DDS et al (2006)[36] In his pilot study indicated that fully edentulous Jaws with various types of bone quality can be treated with high success and good aesthetics using immediately loaded implants featuring a narrow implant apex reduced color height and an anodically oxidized implant surface and that favorable margin bone loss can be maintained.

Vandamme(2007)[44] study also showed that threaded implants offer significant bone-to-implant contact during which may also enhance the secondary stability. Hence, cylinder-type implants seem to be contraindicated for immediate loading regimes due to lowering of primary stability and less resistance to vertical movement and shear stress.

Horwitz(2007) [30]implied in his study the survival and success rates of immediate loaded implants seemed to be similar to those of the traditional protocol. Immediate loading

provided with several advantages such as increased masticatory function, stability to the interim prosthesis, minimizing uncontrolled transmucosal loading, preservation of bone and stimulation of bone remodelling, enhancement of gingival contours and better esthetic. It is also reported with the improvement of psychological impact (34, 35). Despite several advantage of immediate loading, there is no agreement on the technique by which immediate loading can be achieved. The success of immediate loading relies on the technological advances in the texture, shape and material of the implant. In addition to immediate loading the primary stability depends even on the bone quality and density.

Barewal RM(2007) [7] stated the primary stability of implant achieved at the time of implant placement and it is also associated with bone density, length, width and type of implant and drilling technique. The primary stability obtained after implant placement is considered a relevant factor for the prognosis of the implant and has been identified as a prerequisite to achieve osseointegration. This would suggest that high primary stability that makes immediate loading more predictable (20).

Ana vargas Solana etal (2008).[3] evaluated the evidence available in the literature regarding resonance frequency analysis for the determination of primary stability with regard to its utility in decision making in immediate loading protocol and concluded that RFA may help clinician to choose among various loading protocols and to selectively monitor implants during the healing phase.

Romanos GE(2008)[37] have stated the varying designs of implants with various degrees of stability and determine their future clinical performance. Hence, he quoted that screw or "threaded" design minimizes the implants micro motion during function thereby maintaining the PS. Furthermore, a threaded design also increases the surface area of the implant thereby offering a higher percentage of bone-to-implant contacts, in comparison to implants with a cylindrical design. Therefore, threaded type implants are generally recommended and particularly for immediate loading.

EspositoM, Grusovin MG, Willings M, Coulthard P, Worthington HV, Esposito M et al(2009)[18] proposed different time frames for loading dental implants in replacement of missing tooth.

Fawad javed etal (2010) [20] Assessed the role of primary stability for successful immediate loading of dental implants. And its evident that the degree of achieved primary stability during immediate loading protocols is depend on several factors including bone density and quality, implant shape, design, surface characteristics and surgical technique. Further research is required in situation, such as poor bone quality and quantity and multiple implant or augmentation procedure, which may challenge the attainment of primary stability during immediate loading.

Fung LJ et al(2010)[22] have demonstrated the clinical outcome of an implant by many factors, including the implant body, skill of surgeon, and the oral environment. Few other

studies have demonstrated that the quality of the alveolar bone is the most important factor for achieving good primary stability (21).

Heng-Li Huang (2010).[26] Investigated implant stability using resonance frequency measurement of topographically changed and surface chemistry modified implants in rabbit bone. And found that implant surface properties influence RFA measurements of implant stability. surface chemistry modified titanium implants showed higher values than topographically changed implants.

Sun jong kim ,Myung Kim –et al(2010)[41] Proposed in the animal study that the bone to implant contact ratio was higher in surfaces with a roughness of 1.02 [73.6%+14.4%] SLA treated and in surfaces with a roughness of 1.76 [69.6%+ 12.5%] than in surfaces with roughness of 0.86 m[60.82%+13.11]. There were no significant difference between the 3groups of various surfaces in terms of implant stability.

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Fung et al et al(2011)[22] He concluded that after 36 months of functional loading there was no significant difference in the change in radiographic bone levels between titanium oxide- anodized & machined surface MKIV dental implants. From 12 to 36 months of functional loading ,both anodized machined surfaces implants exhibited gains in RBL(Radiographic Bone Level) which statistically significant for the machined implants.

Antonin sinmunek etal (2012) [40]. Monitor the development of stability of immediately loaded implants during early healing and concluded that implant with low primary

stability showed significant increase in stability over time and increase in stability during healing. In contrast, implant with high primary stability lost some stability over time.

Jan gottlow etal (2012)[29]. Experimental investigation was done to compare the bone tissue responses and implant stability between two commonly used implants representing different geometries and surface characteristics. Both HSBA and OX implants were well integrated in bone and showed firm and increased stability from placement to after 6 weeks of healing. The HSBA implant showed more BIC after 10 days and OX implant more BIC after 6week of healing. The HSBA implant showed significantly higher shear strength after 3 and 6weeks and higher RTQ values after 3 weeks than OX implant. This result may be due to difference in surface roughness and hydrophilic properties.

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Gerard torroella saura, Javier mareque etal (2014)[24]. Evaluated the effect of two different designs, tapered vs cylindrical, on primary stability of implants placed with an immediate loading protocol in edentulous mandible to support fixed prosthesis with in occlusal contacts during first 48hr and concluded that tapered implant achieved greater primary stability values measured with ITVs and less marginal bone loss than the cylindrical implants

Alessandiopozi, Marco Talliarico et al (2014) [2]Compared the clinical & radiological outcomes of two implant designs [Noble active & Noble speedy groovy] with different prosthetic interfaces and neck configuration and explained that lower marginal bone loss around that conical connection of noble active implant in comparison with flat to flat implant abutment interface with noble speedy groovy implants. The clinical parameters [SBI &

PS]were absolutely insignificant in well maintained patients & concluded that MBL changes could be affected by the different implant designs A high ISQ values was found for both implants & no statistically significant differences was found for ISQ mean values b/w interventions .

Bilal Al nawas etal (2014)[12]. Investigated in a split mouth model whether small diameter implants made from titanium-13 zirconium alloy perform at least as well as titanium grade IV implants. This study confirms the TiZr small diameter bone level implants provide at least the same out comes after 12 mounths as grade IV bone level implants. This improved mechanical properties of TiZr may extend implant therapy to more challenging situations.

Lester Du Preez et al [32] (2014)conducted a study based on longevity and functionability of three different implant designs – Hydroxyapatite, Ceramics, titanium (Plasma Sprayed/ Pure/Alloy) in the same patient and concluded that different designs of implant system have no bearing on the longevity or functional success of the units used at least in the anterior mandible.

The present in vivo study was conducted for the comparative evaluation of clinical stability of two different types of implants with different surface treatments namely i) Al Oxide blasted / acid etched surface & ii) Resorbable blast medium (RBM) (Calcium phosphate) treated surface loaded immediately with a fixed full arch prosthesis.

The following materials , instruments and equipment were used for the study.

MATERIALS USED:

1. Root form endosteal implants (Al Oxide blasted / acid etched surface)- Touareg-S (Adin implant system, Adin pvt ltd,Israel)
2. Root form endosteal implants (Resorbable blast medium (RBM) (Calcium phosphate) treated surface) - Touareg-OS (Adin implant system, Adin pvt ltd, Israel)
3. Smart peg type 49 (OSSTELL MENTOR, Gothenborg, Sweden).
4. CAD-CAM fabricated Titanium frame work (TDS ME 300 HP,TDS Biotechnologies,Taiwan)
5. Polyether impression material (pentasoft monophase,Pentamix-2,3M ESPE, Seefeld , Germany)
6. Tray adhesive (3M ESPE, Seefeld , Germany)
7. Soft tissue gingival mask (DETAX ,Ettlingen, Germany)
8. Open tray transfers-implant level (Adin implant system, adin pvt ltd, Israel)
9. Implant replicas. (Adin implant system, adin pvt ltd, Israel)
10. Healing collars. (Adin implant system, adin pvt ltd, Israel)
11. Bite registration paste.(exabite , Ivoclar vivadent ,Schaan, Italy)
12. Heat cure acrylic resin. (DPI, Mumbai)

13. Auto polymerizing acrylic resin-pink. (DPI, Mumbai)
14. Auto polymerizing acrylic resin –clear. (DPI, Mumbai)
15. Cross linked acrylic teeth (Gnathostar, Ivoclar Vivadent Inc,NY ,USA) .
16. Stainless steel sleeves.
17. Light cure Composite resin (GC CORPORATION,Tokyo, Japan)
18. 2% lignocaine with adrenalin (1: 200,000) (Lignox, Indoco remedies pvt ltd .Mumbai)
19. Povidone-Iodine solution 2 % (Betadine ,wockhardt,India) .
20. Polyethylene glycol suture (vicryl 3-0ETHICON, Johnson & Johnson, Aurangabad)

INSTRUMENTS USED

1)Implant surgical kit (Adin implant system, adin pvt ltd.,Israel).

-Initial drill (lancet drill)

-2.0mm twist drill -.

-2.8 mm twist drill.

-3.2 mm twist drill.

-3.65 mm twist drill.

Paralleling pin.

Depth gauges (short and long)

2) Implant driver.

3) Hex driver.

4) Caliberated torque wrench.

5) Bard Parker knife no:3

6) Bard parker blade no :15.

7) Howarth's periosteal elevator.

8) Austins retractor.

9) Cheek retractor.

10) Vestibular retractor.

11) Tissue forceps.

12)Needle holder.

13) Scissors.

14) Semiadjustable articulator with facebow (Hanau wide vue, whipmix corp, USA)

EQUIPMENTS:

1. Cone beam CT machine (Cone Beam CT CS 9300,Carestream , France)
2. Implant motor with Physio dispenser (Saeshin, korea)
3. Radio visio graph.(RVG) (Carestream ,France)
4. Resonance frequency analyser -OSSTELL MENTOR (Gothenborg, Sweden)

5. Optical Scanner (Shining 3D, TDS biotechnologies ,Taiwan)
6. TDS ME 300 HP - 5 axis milling machine (TDS biotechnologies ,Taiwan)
7. Pentamix 2 automixing device (3M ESPE ,Seefeld,Germany)

Description of Resonance Frequency Analysis (RFA) & Osstell machine

The RFA technique is essentially a bending test of the bone-implant system in which an extremely small bending force is applied by stimulating a transducer. It is equivalent in terms of direction and type to applying a fixed lateral force to the implant measuring the displacement of the implant. This effectively mimics clinical loading conditions, although on a much reduced scale. The RFA method can potentially provide clinically relevant information about the state of the implant-bone interface at any stage of treatment.

The RFA analyser used in the present study is the Osstell mentor developed by Meredith et al, Gothenburg, Sweden. It consists of a metal rod (Smart peg) attached to the implant with a screw connection. The rod has a small magnet attached to its top that is stimulated by magnetic pulses from a handheld electronic device. The magnetic waves are of sinusoidal form .The rod mounted on the implant has two fundamental resonance frequencies; it vibrates in two directions, perpendicular to each other. One of the vibrations is in the direction where in the implant is most stable. The frequency of the registered oscillation depends on the stiffness of bone – implant attachment. The stiffer the system , the higher the transducer's oscillating frequency will be. Thus two ISQs (Implant Stability Quotient) are provided. The ISQ values are displayed on the screen of the hand held electronic device. For example, an implant with buccally exposed threads may show one low value, reflecting the lack of bone in the buccal-lingual direction, and one high value , reflecting good bone support in the mesial-distal direction.

Usually the average of the two values are taken to be the ISQ of that particular implant . The implant stability quotient is a nearly linear mapping from resonance frequency measured in kHz to the more clinically useful scale of 1-100 ISQ. The higher the ISQ ,the more stable the implant.

METHODOLOGY

I. Formulation of study design
   a. Split mouth prospective trial
   b. Formulation of null hypothesis
   c. Inclusion and exclusion criteria
   d. Informed consent

II. Patient selection

III. Fabrication of complete denture

IV. Fabrication of radiographic template

V. Cone beam CT evaluation

VI. Implant placement

VII. Assessment of primary implant stability

VIII. Fabrication of hybrid prosthesis
   a.impression making
   b.framework trial
   c.jaw relation and wax trial
   d.insertion of hybrid prosthesis

IX. Assessment of implant stability – 1 month , 3 months,6 months and 12 months intervals.

X. Tabulation of data & Statistical analysis.

I. FORMULATION OF STUDY DESIGN :

a. Split mouth prospective trial

The present in-vivo study is designed to be a split mouth prospective clinical trial in which each patient received both the types of implants investigated in either of the two quadrants of the mandibular arch - right or left .Each group of implants was placed on one side of the arch (n-=3) for each patient. A total of 5 patients were included in the study resulting in 15 implants of each group being placed. The Alumina oxide blasted / acid etched surface (TOUAREG-S) is taken as the control (Group A) and the Resorbable blast media (RBM) surface (TOUAREG-OS) is taken as the test group(Group B) . The side selection –right or left for each group is randomized according to the randomization schedule give below.

Table 1 : Randomisation schedule for implant placement

SITE	Intra oral region	Patient 1	Patient 2	Patient 3	Patient 4	Patient 5
I	46-47	A	B	B	A	A
II	44-45	A	B	B	A	A
III	43	A	B	B	A	A
IV	33	B	A	A	B	B
V	34-35	B	A	A	B	B
VI	36-37	B	A	A	B	B

A - Alumina oxide blasted / acid etched surface (TOUAREG-S)

B - Resorbable blast media (RBM) surface (TOUAREG-OS)

The study is a triple blind Prospective clinical trial in which the subject, operator and investigator are blinded. An independent research associate prepares the randomization schedule and hands over the implant accordingly to the operator during implant placement. The assessment of the clinical stability is again done by an independent investigator who measures the stability at fixed time intervals namely

a. Immediately after implant placement.
b. One month after implant placement.
c. Three months after implant placement.
d. Six months after implant placement.
e. Twelve months after implant placement.

b.Formulation of the null hypothesis.

Null hypothesis for this study is that there is no difference in the clinical stability of the two implant surfaces over a period of one year.

c. Inclusion and exclusion criteria.

Inclusion and exclusion criteria for Participation in the study

Inclusion criteria

- Voluntary informed consent
- Age ≥45 years and ≤ 65 years
- Completely edentulous maxilla and mandible at the time of surgery
- Last tooth extracted more than 8 weeks before date of surgery

- Available bone height of atleast 10 mm in the molar region, 13 mm in the premolar region and 16 mm in the canine region of the edentulous mandible.
- Available bone width of atleast 7mm in molar region, 6 mm in premolar region and 6 mm in canine region of the edentulous mandible.
- Commitment to participate in the study for atleast 1 year of follow-up examinations

Exclusion criteria (systemic)

- Medical conditions requiring prolonged use of steroids
- Severe hemophilia
- Bisphosphonate medication
- History of leukocyte dysfunction and deficiencies
- History of head and neck radiation or chemotherapy
- History of renal failure
- History of uncontrolled endocrine disorders
- Physical handicaps interfering with ability to perform adequate oral hygiene
- Use of any investigational drug or device within 30 days prior to implant surgery
- Alcoholism or drug abuse
- HIV infection
- Smoking >10 cigarettes or cigar equivalents per day or chewing tobacco> 10 cigarette equivalents per day .
- Conditions or circumstance which would prevent completion of study participation or interfere with analysis of study results (eg. Non- compliance)

Exclusion criteria (local)

- Local inflammation including denture stomatitis.
- Mucosal diseases such as erosive lichen planus
- History of local irradiation therapy
- Presence of osseous lesions
- Unhealed extraction sites
- History of bone reconstruction and bone grafting techniques at site of intended implant placement.
- Severe bruxing or clenching habits
- Persistent intraoral infection
- Patients with inadequate oral hygiene or unmotivated for adequate home care

Exclusion criteria (secondary)

- Need for GBR treatment at implant surgery
- Insufficient bone or any other bone abnormality that contraindicated placement
- Inappropriate treatment according to study protocol.
- Lack of primary implant stability at time of abutment connection (ie, spinning implant at 35 Ncm torque or laterally moving implant)

d.Informed consent. (Annexure 1)

The study proposal was presented before the ethical committee and institutional review board of the study center and clearance was obtained for the proposal. All the subjects who fulfilled the above inclusion and exclusion criteria were counselled regarding the treatment options and the research element involved in it. They

were free to ask any questions and were clarified. A written consent was obtained from those subjects who were willing to participate in the study.

II.PATIENT SELECTION :

The completely edentulous patients who reported to the department of prosthodontics of the study center were screened to fulfill the inclusion and exclusion criteria. A detailed general examination and local examination was done for the prospective study population. A panoramic radiograph as a part of the routine investigation for complete denture therapy is also obtained. Based on these clinical and radiographic assessments, the final safety population of five patients (male = 4, female =1) was selected.

III.FABRICATION OF COMPLETE DENTURE :

A conventional complete denture was constructed for each patient. Preliminary impression trays were made with stock tray using irreversible hydrocolloid impression material (alginate – Algitex ,DPI ,India). Special trays were constructed using auto polymerising polymethyl methacrylate resin (DPI, India). Border moulding is done with low fusing compound (DPI, India) and final impressions were made with medium body polyether impression material (Pentamix-2,3M ESPE) . Wax occlusal rims (Hindustan dental, India) were constructed on record bases and face bow transfer (hanau spring bow, whipmix corp, USA) was done. Centric jaw relation was recorded and the casts were mounted in a semi adjustable articulator(Hanau wide vue, whipmix corp, USA) .Teeth arrangement was done using anatomical tooth form (Gnathostar,Ivoclar Vivadent Inc,NY ,USA) employing the standard principles. Trial set up was verified in the patient's mouth for aesthetics , phonetics and occlusion and was then processed in heat polymerizing polymethyl methacrylate resin(DPI, India).The dentures were then inserted in

the patient's mouth and the necessary occlusal adjustments were done clinically. The patients were instructed regarding denture wear and maintenance.

IV.FABRICATION OF RADIOGRAPHIC TEMPLATE

Patients were recalled after one week and the lower denture was alone then duplicated in clear auto polymerizing acrylic resin(DPI, India). The duplication was done by investing the denture in a duplicating flask. Radio-opaque markers (gutta percha) were placed along the long axis of the canine, pre molar and molar teeth extending the whole length from the occlusal surface to the denture base. Thus a radiographic template was obtained to evaluate the bone volume in the area of interest..

V. Cone Beam CT EVALUATION

A cone beam computerized tomographic evaluations (Cone Beam CT CS 9300,Carestream , France) of the mandible was done with the patient wearing the radiographic template. The images were then analyzed for three dimensional evaluation of bone quality in the pre determined site for the implant placement. The available bone height, mesio distal and bucco lingual width at each site was noted down in the clinical case record of the patient. One subject who showed deficient bone volume in the posterior mandible was relieved from the study and one more patient was added who fulfilled the eligibility criteria.

VI.IMPLANT PLACEMENT :

A surgical template was fabricated from the radiographic template by removing the radio opaque marker with a rotary cutting instrument and the channels where the markers

were placed earlier were widened to accommodate 2mm wide hollow stainless steel metal sleeves . The sleeves were secured in position by flowing a thin mix of clear auto polymerizing resin into the channels and then inserting the sleeves into the channels. The guiding sleeves were placed only in the areas of proposed implant placement and serve as a guide to position the pilot drill for intial osteotomy. The surgical template thus obtained was cold sterilized by immersion in 2 % gluteraldehyde solution(cidex) for 20 minutes.

1. The patients were given a single oral dose of 2 g Amoxycillin (Mox 500,Ranbaxy ,India) one hour before the implant sugery. Skin disinfection was done with povidone iodine paint (Betadine ,wockhardt,India). The patient was asked to rinse the mouth with 2% chlorhexidine mouthwash (Rexidin ,ICPA,India) for 3 to 5 minutes. Surgical draping was done . Local anesthesia was achieved with 2 % lignocaine with adrenalin 1 : 200,000 (Lignox, Indoco remedies, Mumbai) infiltrated along the buccal and lingual aspects of the mandible. No nerve block was given. The surgical template was placed over the edentulous mandibular ridge and pilot osteotomies were done .The surgeon made sure the pilot drills were inside the bone by tactile sensation and measuring the drill depth and correlating it with the CBCT measurements. The surgical guide was then removed and a crestal incision was made with BP blade no 15 and a full thickness mucoperiosteal flap was reflected. The pilot osteotomies made earlier were identified by the bleeding points and also by probing. Sequential osteotomies were done with successive drills in each site to specifically accommodate the predetermined implant sizes as given below :

Table 2 : Intra oral sites and corresponding implant dimensions

SITE	Intra oral region	Implant length	Implant diameter
I	46-47	8 mm	4.2 mm
II	44-45	11.5 mm	3.75 mm
III	43	13 mm	3.75 mm
IV	33	13 mm	3.75 mm
V	34-35	11.5 mm	3.75 mm
VI	36-37	8 mm	4.2 mm

The osteotomies were prepared using a contraangle surgical handpiece (NSK corporation, Japan) mounted on an implant motor (Saeshin, korea) under copious irrigation of cold normal saline(Dexter laboratories , India) under 800 to 1200 rpm speed . All the osteotomies on one side of the arch were completed first and the implants were inserted before the contralateral side osteomies were started.

The implants were assigned to site by the independent research assistant according to the randomization schedule prepared earlier. The implant group and size were verified and the implants were uncovered from the outer package by the research assistant and only the sterile glass vials containing the implants were handed over to the surgeon. The operator bias was thus eliminated since both groups of implants look similar macroscopically.

All the implants were placed by the same surgeon for all the study participants inorder to eliminate inter operator bias.

VII . ASSESSMENT OF PRIMARY IMPLANT STABILITY

The implants were hand torqued in place and were indexed for favourable emergence. The insertion torque value for each implant was measured in N Cm by means of the calibrated torque wrench and was noted down as assessed by the surgeon. The calibrated torque wrench has readings corresponding to values of 35 Ncm , 50 Ncm,70 Ncm and 100 Ncm. The insertion torque values were taken in reference to the nearest calibration .For example , an ITV between 35 and 50 Ncm is considered to be as >35 Ncm. No definitive numerical value can be obtained but a range is obtained for each implant and scores are assigned based on these ranges. (table no.6)

The Implant stability quotient (ISQ) values were assessed using the Resonance frequency Analyser ,(RFA) (Osstell Mentor,Gotenborg,,Sweden) by the investigator who will also measure the periodical ISQ values throughout the study. The measurement of ISQ values begins with connection of a smart peg (type 49 ,Osstell Mentor, Gotenborg, Sweden) to the implant. The smart peg is a wireless magnetic transducer designed to fit the internal hexagon of the implant and is screwed into place by an attached handle. They are finger tightened and the RFA probe was then placed in close proximity to the smart peg on the buccal side .Care was taken not to touch the smart peg with the probe . The ISQ value displayed on the screen of the RFA instrument was recorded. The same procedure was carried out on the mesial side and the ISQ value obtained. The procedure is then repeated for all the implants one at time and ISQ values noted down.

After assessment of the primary stability of the implants as described above , the implants were covered with a healing collars which were atleast 1 mm above the peri implant soft tissue. Flap closure was obtained by means of multiple interrupted sutures using polyethylene glycol (vickryl, ethicon, India). The patients were prescribed a course of antibiotics (amoxycillin) for 5 days and analgesics (ketorolac) for 3 days. They were also instructed to use 2 % chlorhexidine mouthwash twice daily for 1 month postoperatively.

VIII.FABRICATION OF HYBRID PROSTHESIS

The implants were subjected to immediate functional loading within 1 week of placement. An implant level screw retained metal – acrylic hybrid prosthesis was fabricated as follows :

A.IMPRESSION MAKING:

After completion of suturing, the healing collars were removed one by one and implant level open tray transfers were connected. The open tray transfers were splinted together using pattern resin .The resin connection was sectioned in between the implants and were connected together again so as to minimize polymerization shrinkage and facilitate accurate transfer of relative implant positons. A special tray was fabricated from auto polymerising resin from the pre operative edentulous cast. The tray was tried in the patients mouth and necessary adjustments were made so as to facilitate proper seating of the tray and coverage of the tray transfers. Tray adhesive was applied and impression was made with medium body polyether impression material (pentasoft monophase) using automixing device(pentamix 2).Impression was removed from the patients mouth by loosening the guide pins of the tray transfers. The healing collars were then replaced in the patients mouth.Implant replicas were connected to the

impression and soft tissue mask was poured. A working model is obtained by pouring type III dental stone (kalabhai, India).

B.FRAMEWORK TRIAL

The model was scanned with a scanner (shining 3D , TDS biotechnologies ,Taiwan) and an implant level titanium milled frame work was obtained.(TDS ME 300 HP - 5 axis milling machine., TDS biotechnologies ,Taiwan).The CAD-CAM fabricated metal framework is tried on the second or third post operative day and a panaromic radiograph is taken to verify the fit of the frame work.

C) JAW RELATION AND WAX TRIAL

A Wax occlusal rim was fabricated on the metal frame work and jaw relation was made opposing the existing maxillary denture. Esthetics , phonetics , occlusal plane and vertical dimension were established. Centric relation record was obtained opposing the existing maxillary denture using Bite Registration paste (exa bite,GC ASIA).The model and the existing maxillary denture were mounted in a semi adjustable articulator using this jaw relation record. Teeth arrangement(Gnathostar,Ivoclar Vivadent Inc,NY ,USA) was done and a wax trial was seen in the patients mouth. A Lingualised occlusal scheme was obtained .

D) INSERTION OF HYBRID PROSTHESIS

The wax trial was processed in heat polymerized acrylic resin and metal acrylic hybrid prosthesis is obtained. The prosthesis is designed to be without any flanges or palatal plate. A slight tissue contact with the edentulous ridge is maintained by the smooth , convex inner surface of the hybrid prosthesis. On the sixth or seventh postoperative day the hybrid prosthesis was inserted in the patients mouth and the prosthetic screws were torqued to 15 Ncm

using calibrated torque wrench. Occlusion was verified and minor occlusal adjustments if any was done in the dentures. The screw access channels in the hybrid denture were closed with a plug of cotton and light cure composite resin . The patient was instructed on oral hygiene maintenance and advised to restrain chewing very hard food items. However the patient was advised to continue his normal food habits. Patients were counseled regarding the recall visits and their continued participation in the study.

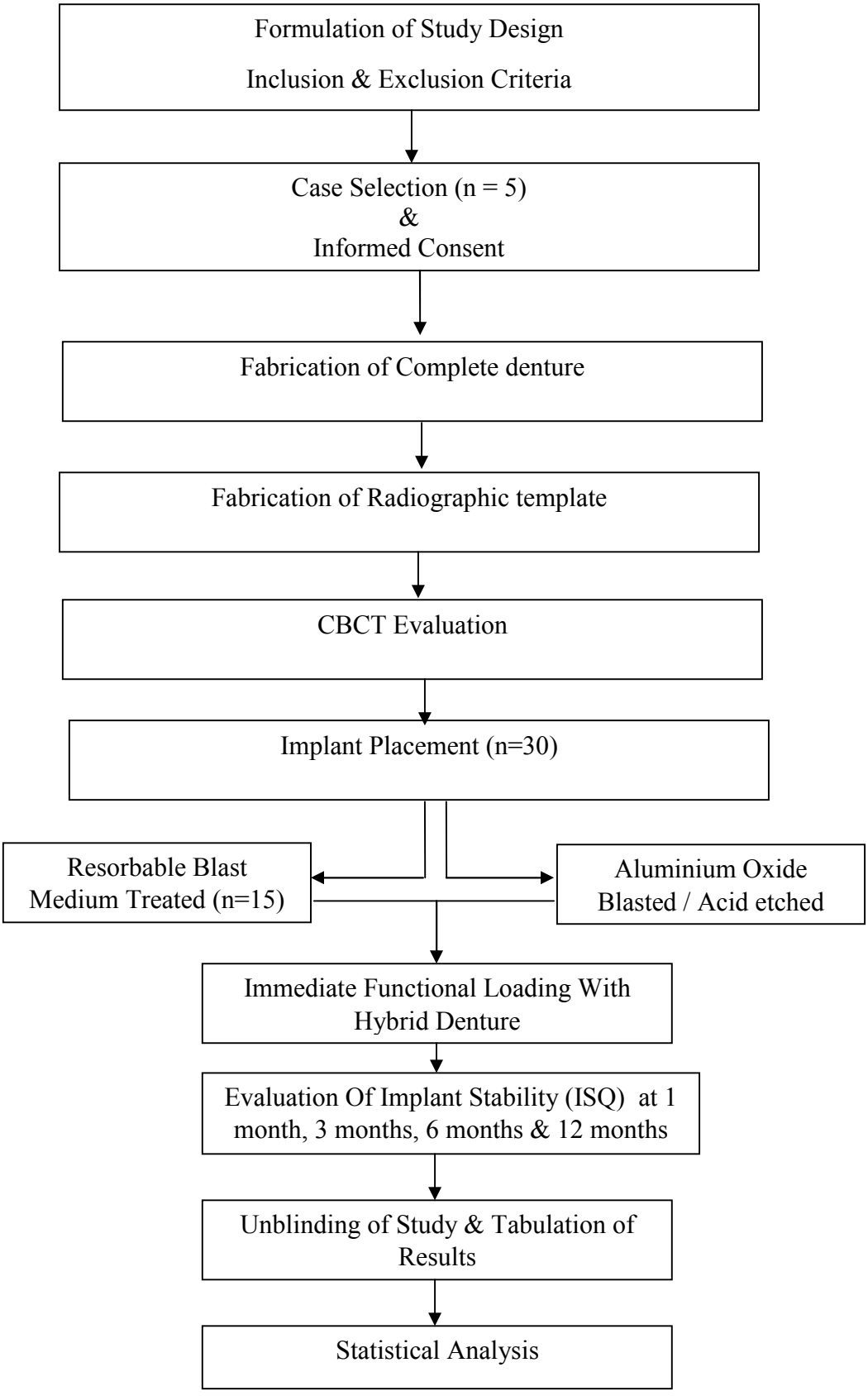
IX. Assessment of implant stability – 1 month , 3 months,6 months and 12 months intervals

The patients were recalled at an interval of 1 month after implant placement and immediate loading with metal – acrylic hybrid prosthesis. The prosthetic screws were accessed by removing the composite resin over the screw access channels with an airotor mounted tungsten carbide bur . The cotton pellet is also removed and the prosthetic screws were disengaged one by one using a hand wrench. The hybrid prosthesis is removed from the implant heads and the exposed implant internal hexagons are irrigated with saline solution. The smart pegs are attached at the implant level and ISQ values are obtained using the Resonance Frequency Analyser in a manner similar to that obtained during implant placement. The measurement is done by the blinded investigator and noted down .The prosthesis is then screwed back in place and patient is instructed regarding the subsequent follow up visit. ISQ values were obtained in a similar manner for periods of 1 month , 3 months , 6 months and 12 months after implant insertion and immediate prosthetic loading.

X.Tabulation of data & Statistical analysis

The study was unblinded after 12 months and the ITV and ISQ values were tabulated according to the study groups. The tabulated data was subjected to statistical analysis to fulfill the objectives of the study and to test the null hypothesis. Statistical analysis was done using the software SPSS version 16.

METHODOLOGY – OVERVIEW



Materials and Methods

Results

The present in vivo study was conducted for the comparative evaluation of clinical stability of two different types of implants with different surface treatments namely i) Al Oxide blasted / acid etched surface & ii) Resorbable blast medium (RBM) (Calcium phosphate) treated surface loaded immediately with a fixed full arch prosthesis.

The test samples (implants) were grouped as follows :

Group A - Al Oxide blasted / acid etched surface (Touareg S) (n=15)

Group B - Resorbable blast medium (RBM) (Calcium phosphate) treated surface (Touareg OS) (n=15).

The samples were placed in 5 patients who received 3 implants of each group in either of the two quadrants of the mandibular edentulous ridge (split mouth design). The initial and progressive stability of these two groups of implants were assessed and the results obtained are tabulated as follows :

Table 3: Insertion torque values (ITV) in NCm

Case no	Site I	Site II	Site III	Site IV	Site V	Site VI
Case 1	>50	50	50	70	>50	70
Case 2	>35	70	70	50	50	50
Case3	>70	>70	70	70	50	50
Case 4	>70	>35	70	>70	>35	50
Case 5	>50	70	70	70	>50	>50

Table 4 : Insertion torque values (ITV) in NCm for Al oxide blasted / acid etched surface

Case 1	>50
	50
	50
Case 2	50
	50
	50
Case 3	>70
	>70
	70
Case 4	>70
	>35
	50
Case 5	>50
	70
	70

Table 5 : Insertion torque values (ITV) in NCm for Resorbable blast medium treated surface

Case 1	70
	>50
	70
Case 2	>35
	70
	70
Case 3	70
	50
	50
Case 4	>70
	>35
	70
Case 5	70
	>50
	>50

Table 6 : Insertion torque Values and corresponding Scores.

ITV RANGE (NCm)	SCORE
0 – 35	0
36 - 50	1
51 – 70	2
71 – 100	3

Table 7 : Comparison of Insertion torque values (ITV) of Al Oxide blasted / acid etched surface (Group A) and Resorbable blast medium (RBM) treated (Group B) implants

Group	N	Mann – whitney U value	P value
A	15	102.500	0.34
B	15		

Table 8: Site specific Implant Stability Quotient (ISQ) values

	SITE		0 MONTHS	1 MONTH	3 MONTHS	6 MONTHS	12 MONTHS
CASE 1	I	B	71	50	68	78	79
		M	68	51	77	80	80
	II	B	68	58	71	75	79
		M	72	60	63	77	77
	III	B	55	51	70	75	74
		M	63	55	56	72	76
	IV	B	75	58	71	79	80
		M	77	59	70	82	83
	V	B	70	57	66	79	76
		M	72	58	69	78	79
	VI	B	75	53	64	77	75
		M	74	54	68	78	78
CASE 2	I	B	65	52	68	70	74
		M	72	59	70	75	79
	II	B	62	51	65	68	70
		M	69	58	60	65	69
	III	B	66	52	70	75	75
		M	69	54	68	72	70
	IV	B	51	49	64	70	72
		M	74	55	72	76	76
	V	B	61	51	65	71	72
		M	62	54	68	70	69
	VI	B	64	55	70	74	72
		M	52	48	72	76	78
CASE 3	I	B	75	55	71	74	79
		M	80	58	75	76	80
	II	B	65	59	76	76	80
		M	70	58	78	78	76
	III	B	80	58	79	80	80
		M	78	59	77	79	79
	IV	B	75	56	76	77	74
		M	77	58	74	78	79
	V	B	70	54	72	75	75
		M	72	58	74	79	80
	VI	B	75	51	68	81	82
		M	74	56	79	80	80

B- Buccal M- Mesial

Table 8 Continued:

	SITE		0 MONTHS	1 MONTH	3 MONTHS	6 MONTHS	12 MONTHS
CASE 4	I	B	75	58	65	73	75
		M	80	59	70	77	76
	II	B	65	52	66	75	76
		M	70	54	72	79	78
	III	B	80	62	74	80	80
		M	78	60	75	79	80
	IV	B	75	58	71	79	78
		M	77	59	70	82	80
	V	B	70	57	66	79	79
		M	72	58	69	78	80
	VI	B	75	53	64	77	76
		M	74	54	68	78	78
CASE 5	I	B	68	50	70	72	72
		M	66	52	68	70	70
	II	B	62	53	65	74	72
		M	65	51	68	72	70
	III	B	68	55	70	74	76
		M	67	52	72	75	75
	IV	B	66	54	69	74	78
		M	68	54	68	78	78
	V	B	64	53	68	80	79
		M	61	50	69	81	80
	VI	B	60	51	70	78	78
		M	63	52	70	80	81

B- Buccal M- Mesial

Table 9 : Implant Stability Quotient (ISQ) values for Al oxide blasted / acid etched surface (group A)

	SITE	0 MONTH	1 MONTH	3 MONTHS	6 MONTHS	12 MONTHS
CASE 1	1	69.5	50.5	72.5	79	79.5
	2	70	59	67	76	78
	3	59	53	63	73.5	75
CASE 2	4	62.5	52	68	73	74
	5	61.5	52.5	66.5	70.5	70.5
	6	58	51.5	71	75	75
CASE 3	4	76	57	75	77.5	76.5
	5	71	56	73	77	77.5
	6	74.5	53.5	73.5	80.5	81
CASE 4	1	77.5	58.5	67.5	75	75.5
	2	67.5	53	69	77	77
	3	79	61	74.5	79.5	80
CASE 5	1	67	51	69	71	71
	2	63.5	52	66.5	73	71
	3	67.5	53.5	71	74.5	75.5

Table 10 : Implant Stability Quotient (ISQ) values for Resorbable blast medium treated surface (group B)

	SITE	0 MONTHS	1 MONTH	3 MONTHS	6 MONTHS	12 MONTHS
CASE 1	4	76	58.5	70.5	80.5	81.5
	5	71	57.5	67.5	78.5	77.5
	6	74.5	53.5	66	77.5	76.5
CASE 2	1	68.5	55.5	69	72.5	76.5
	2	65.5	54.5	62.5	66.5	69.5
	3	67.5	53	69	73.5	72.5
CASE 3	1	77.5	56.5	73	75	79.5
	2	67.5	58.5	77	77	78
	3	79	58.5	78	79.5	79.5
CASE 4	4	76	58.5	70.5	80.5	79
	5	71	57.5	67.5	78.5	79.5
	6	74.5	53.5	66	77.5	77
CASE 5	4	67	54	68.5	76	78
	5	62.5	51.5	68.5	80.5	79.5
	6	61.5	51.5	70	79	79.5

Table 11 : Comparison of mean implant stability quotient (ISQ) values of Al Oxide blasted / acid etched surface (Group A) at different time intervals

	N	MEAN	STANDARD DEVIATION	F VALUE	'p' VALUE
0 month	15	68.2667	6.58425	67.233	.000**
1 month	15	54.2667	3.23412		
3 months	15	69.8000	3.47337		
6 months	15	75.4667	2.99086		
12 months	15	75.8000	3.23927		
total	75	68.7200	8.84026		

Table 12 : post hoc comparison of implant stability quotient (ISQ) of Al Oxide blasted / acid etched surface (Group A) at different time intervals

Tukey's HSD test

(I)	(J)	Mean Difference (I-J)	Std. Error	Sig.
0 month	1 month	14.00000*	1.50833	.000
	3month	-1.53333	1.50833	.847
	6months	-7.20000*	1.50833	.000
	12months	-7.53333*	1.50833	.000
1 month	0 month	-14.00000*	1.50833	.000
	3month	-15.53333*	1.50833	.000
	6months	-21.20000*	1.50833	.000
	12months	-21.53333*	1.50833	.000
3month	0 month	1.53333	1.50833	.847
	1 month	15.53333*	1.50833	.000
	6months	-5.66667*	1.50833	.003
	12months	-6.00000*	1.50833	.002
6months	0 month	7.20000*	1.50833	.000
	1 month	21.20000*	1.50833	.000
	3month	5.66667*	1.50833	.003
	12months	-.33333	1.50833	.999
12months	0 month	7.53333*	1.50833	.000
	1 month	21.53333*	1.50833	.000
	3month	6.00000*	1.50833	.002
	6months	.33333	1.50833	.999

Table 13 : Comparison of mean implant stability quotient (ISQ) values of Resorbable blast medium (RBM) treated surface (Group B) at different time intervals

	N	MEAN	STANDARD DEVIATION	F VALUE	'p' VALUE
0 month	15	70.6667	5.44343	77.560	.000**
1 month	15	55.5000	2.59808		
3 months	15	69.5667	4.02611		
6 months	15	76.8333	3.77334		
12 months	15	77.5667	3.04647		
total	75	70.0267	8.84395		

Table 14 : Post hoc comparison of implant stability quotient (ISQ) of Resorbable blast medium (RBM) treated surface (Group B) at different time intervals

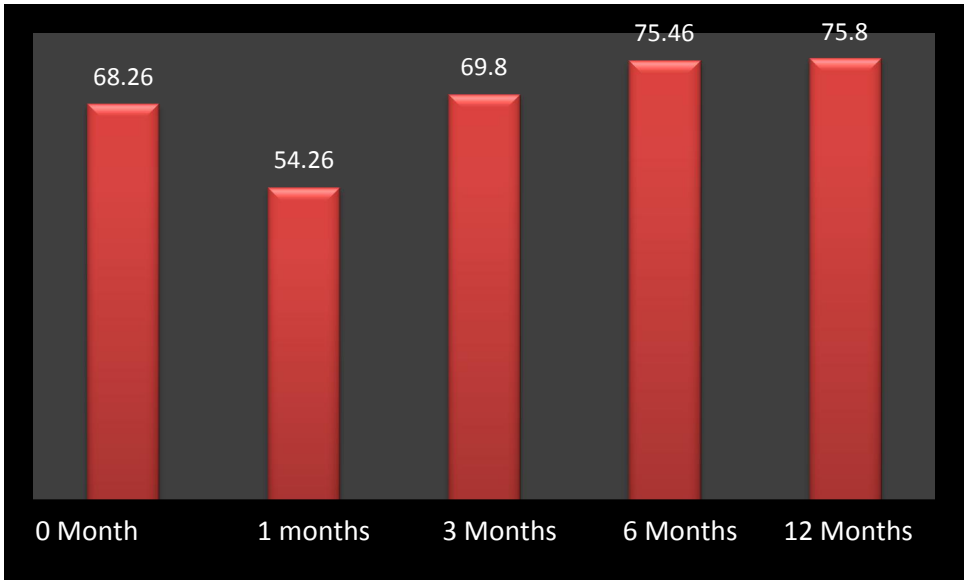
Tukey's HSD test

(I)	(J)	Mean Difference (I-J)	Std. Error	Sig.
0 month	1 month	15.16667*	1.42464	.000
	3month	1.10000	1.42464	.938
	6months	-6.16667*	1.42464	.000
	12months	-6.90000*	1.42464	.000
1 month	0 month	-15.16667*	1.42464	.000
	3month	-14.06667*	1.42464	.000
	6months	-21.33333*	1.42464	.000
	12months	-22.06667*	1.42464	.000
3month	0 month	-1.10000	1.42464	.938
	1 month	14.06667*	1.42464	.000
	6months	-7.26667*	1.42464	.000
	12months	-8.00000*	1.42464	.000
6months	0 month	6.16667*	1.42464	.000
	1 month	21.33333*	1.42464	.000
	3month	7.26667*	1.42464	.000
	12months	-.73333	1.42464	.986
12months	0 month	6.90000*	1.42464	.000
	1 month	22.06667*	1.42464	.000
	3month	8.00000*	1.42464	.000
	6months	.73333	1.42464	.986

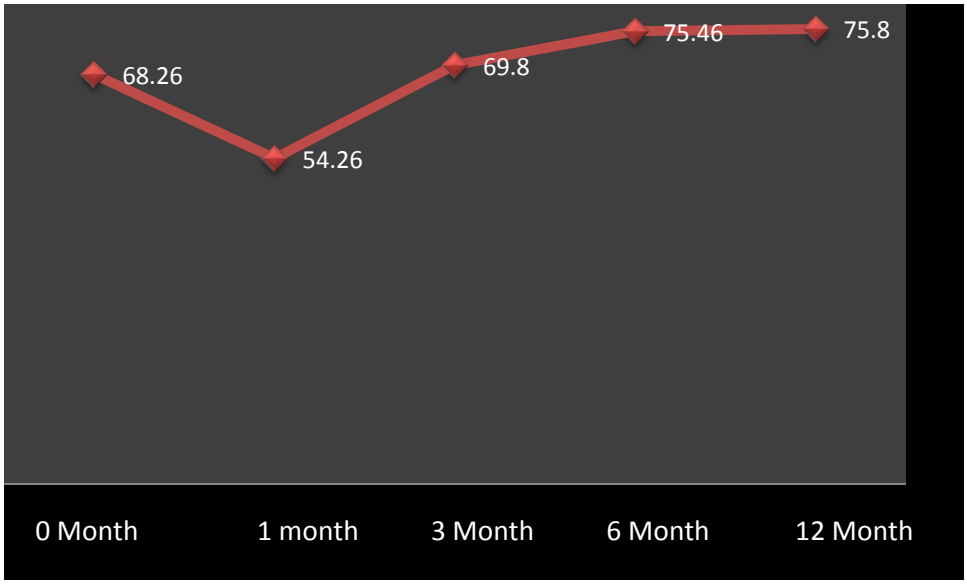
Table 15 : Comparison of implant stability quotients (ISQ) of Al Oxide blasted / acid etched surface (Group A) and Resorbable blast medium (RBM) treated surface (Group B) implants at different time intervals.

Time period	Group	N	Mean	SD	F	p
0 month	A	15	68.267	6.5843	0.383	0.541
	B	15	70.667	5.4434		
1 month	A	15	54.267	3.2341	0.676	0.418
	B	15	55.500	2.5981		
3months	A	15	69.800	3.4734	0.002	0.962
	B	15	69.567	4.0261		
6 months	A	15	75.47	2.991	0.181	0.674
	B	15	76.83	3.773		
12 months	A	15	75.80	3.239	0.294	0.592
	B	15	77.57	3.046		

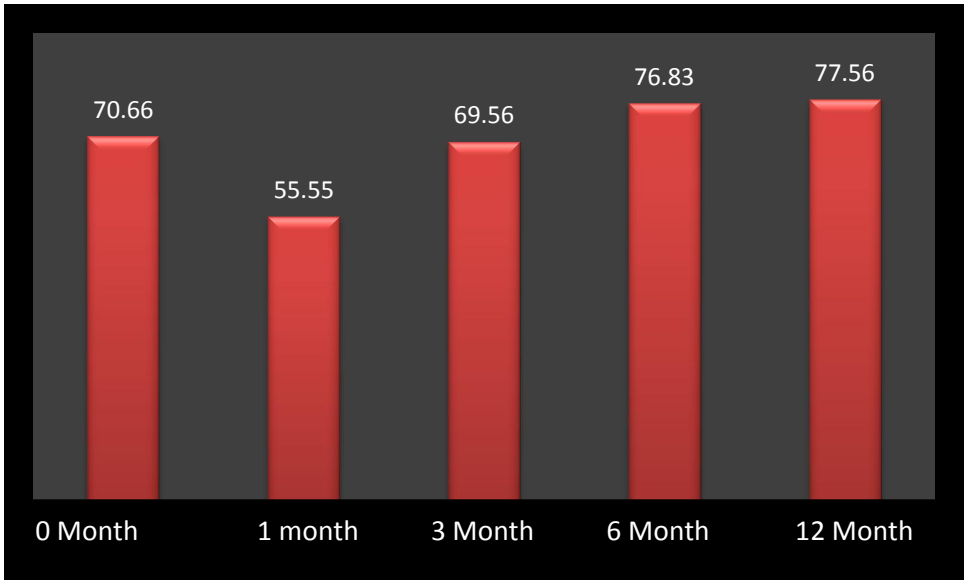
Graph 1 : Mean ISQ values of Al Oxide blasted / acid etched surface (Group A)



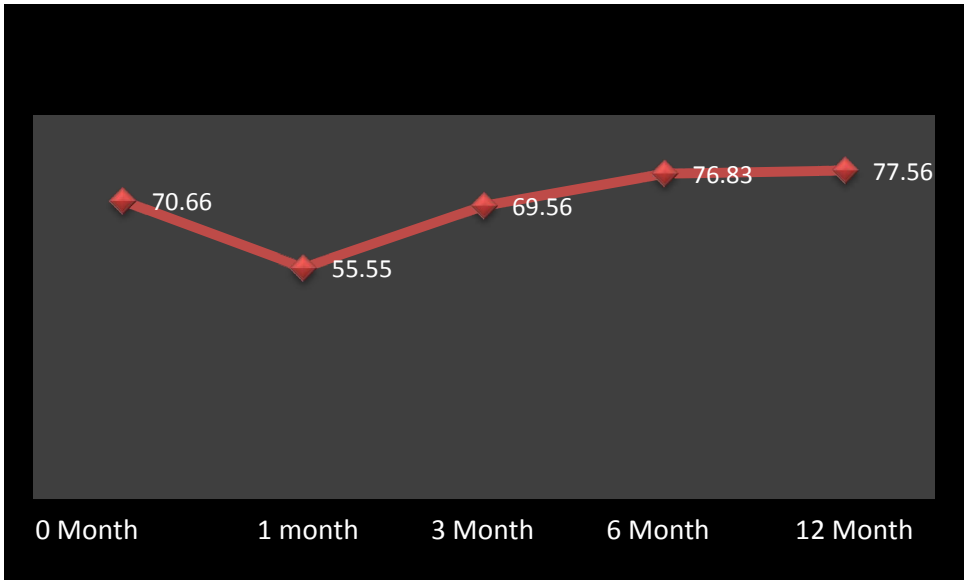
Graph 2 : Change in ISQ over 1 year period for Al Oxide blasted / acid etched surface (Group A)



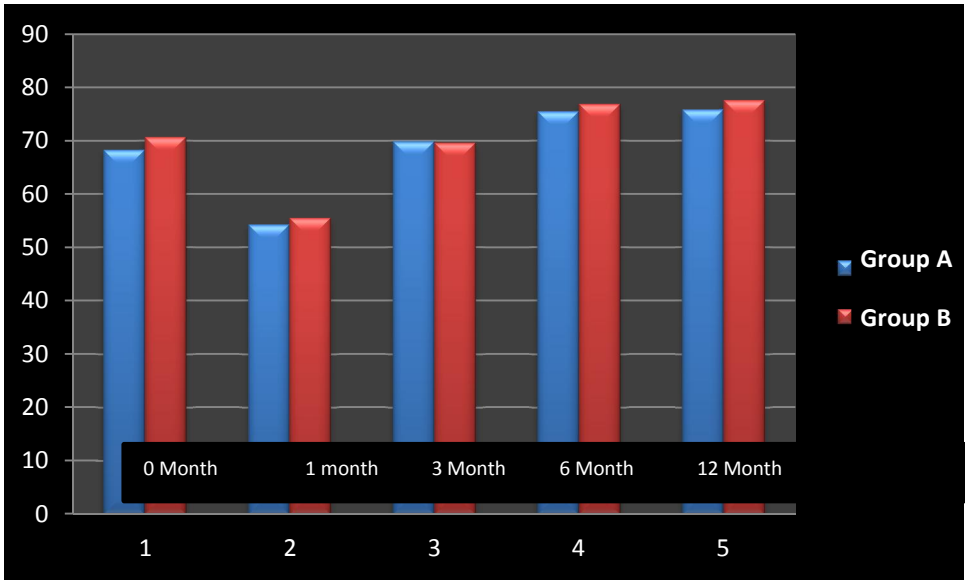
Graph 3: Mean ISQ values of Resorbable blast medium (RBM) treated surface (Group B)



Graph 4 : Change in ISQ over 1 year period for Resorbable blast medium (RBM) treated surface (Group B)



Graph 5 : Comparison of ISQ values of Al Oxide blasted / acid etched surface (Group A) and Resorbable blast medium (RBM) treated surface (Group B) implants at different time intervals.



Discussion

The search for fixed functional and esthetic replacements for missing natural teeth led to the introduction and subsequent widespread use of dental implants. Continued research and innovation in implant biomaterials, macro and micro design , surgical technique and prosthetic options have revolutionalised the field of implant dentistry . Of these , surface modification of endosteal implants received great attention among many researchers[1,7,33,44]. Attempts to modify implant surfaces were aimed at achieving better integration at cellular level , obtaining good primary stability , shortening treatment time etc.The above mentioned aspects have been studied by many authors by employing invitro , histological and clinical models .Many commercial dental implant manufacturers have developed and patented unique surface treatments and claim superior results . However the validity of the claim has to be verified by scientific means . Most of the studies regarding implant surface treatments and their role in achieving and maintaining implant stability have been carried out in either animal models or artificial bone models .Prospective controlled human clinical trials on implant surface treatments are few and limited.

With this background , the present clinical study was done to evaluate the primary and secondary implant stabilities of two different surface treated implants and to compare the difference in stabilities of these two groups of implants . The present study was designed to be a prospective controlled clinical trial employing a split mouth design .Split mouth designs have many advantages over other clinical study protocols such as elimination of intra subject bias , standardization of host environment , easy distribution of test samples etc [4].The completely edentulous mandibular arch was chosen for implant placement in this study. This is because the bone quality in the mandible is predominantly of D1 and D2 types [4,16]. Hence standardization of surgical procedure for implant placement is better and there is hardly any need

to improve the bone quality by use of condensing osteotomes as is the case with edentulous maxilla many a times .Also retention can be poor for mandibular complete denture when compare with maxillary because of the anatomy , pattern of resorption , tongue position and movement and attachment of muscles. Hence the need to improve the retention of mandibular complete denture is more pronounced and this can be achieved either by means of removable overdentures or fully fixed hybrid dentures. Accordingly the subjects in this study were prescribed a mandibular full arch fixed prosthesis supported by six axially placed root form endosteal implants opposing a conventional removable maxillary complete denture .

The study was triple blinded – the subject , the surgeon(operator) and the investigator were blinded so as to eliminate bias at all levels. Since all the implants placed in this study have the same macro design and there is no visible difference in their surfaces clinically, the operator cannot identify the group to which the implant belongs to .Furthermore, the surgical technique is the same for the placement of both the groups of implants. Investigator bias is eliminated by identifying the implants based on their sites of placement only. The values are then assigned to the particular sample and group by the independent research assistant.

Immediate loading of all the implants was done with a metal reinforced acrylic hybrid prosthesis inserted within a week of implant placement in accordance to the ITI guide lines .(ITI consenus statement on loading protocols - 2012) . An implant level screw retained , milled titanium frame work was fabricated since all the implants were axially placed.

Primary stability of implants were measured and expressed in two ways : i) insertion torque value ITV and ii) implant stability quotient(ISQ). The ITVs for Group A - Al Oxide blasted / acid etched surface (Touareg S) (n=15) and Group B - Resorbable blast medium (RBM) (Calcium phosphate) treated surface (Touareg OS) (n=15) were compared using Mann – whitney test for non parametric data and there was no statistically significant difference between the two groups ($p = 0.34$). All the implants achieved an ITV of >35 N cm , thus fulfilling the inclusion criteria and criteria for immediate functional loading. The mean ISQ at the time of implant placement for Group A - Al Oxide blasted / acid etched surface (Touareg S) was found to be 68.267 and that of Group B - Resorbable blast medium (RBM) (Calcium phosphate) treated surface (Touareg OS) was found to be 70.667. There was no statistically significant difference between the ISQ s of two groups immediately after placement (primary stability) ($p = 0.54$). The lack of difference in primary stabilities of the two groups can be attributed to the fact that both the groups of implants have similar sizes, geometry and macro design.This finding is in accordance with previous studies such as the one by Torroella et al where RFA was not able to detect major differences in implant primary stability between the two implant designs[24]. Primary implant stability has been proven to be a mechanical phenomenon .On the other hand , Secondary stability occurs through a cascade of biologic evens sucha s bone regeneration and remodeling at the bone implant interface.

Another study by Alessandiopozi et al in 2014 affirmed that RFA measurements present false positive results because it cannot detect the bone – implant contact at deeper parts[2]. So it can happen that an implant inserted in a thin cortical bone but with high density bone at the apical part had acceptable ITV but low ISQ values. However Bischof et al in 2004 found that the diameter does not affect the ISQ values[13].

Primary stability is primarily important for implant osseointegration. The lack of primary stability has openly been assumed to be the cause factor for the early implant failure. (Esposito et al 1998)[18]. Achieving stability depends on the bone quality , surgical technique and the micro and macro design of the implant used . Thus implant stability is the key to clinical success (Gapski et al 2013) [23].Optimal implant stabilization is especially essential for immediate loading. It is known that implant primary stability depends on the bone quality , surgical technique and implant design. Implant design plays an important role in primary intra osseous stabilization. The wide diameter and long implants are recommended in cases of poor bone density situations.[26,40]

In the present study , there was a statistically significant difference among the implant stability quotient (ISQ) values of Al Oxide blasted / acid etched surface (Group A) at different time intervals (p = 0.000). The same was noted in case of implant stability quotient (ISQ) of Resorbable blast medium (RBM) treated (Group B) at different time intervals (p =0.000). The increase in ISQ values over a one year period can be attributed to the fact that improved osseointegration at the cellular level led to enhanced bone – implant contact (BIC) which inturn increased the stability and stiffness of the implant – bone complex. However a decrease in the ISQ values of both the group of implants were noted at a period of 1 month post operatively. Earlier investigations showed that during the healing process, mechanical anchorage of the implant in bone weakens. Conversely , biologic stability of the implant increases. This is in concurrence with many of the previous studies.[32,35,38,40]

A few groups of authors have indicated that changes in stability during healing were mainly dependant on the initial stability level of an implant. In their 12 week

clinical study, Nedir et al found that ITI implants with a pISQ les thsn 60 exhibites an increase in stability whereas implant with apISQ of 60 -69 exhibited decrease stability ater 8 weeks[13]. At the end of 12 weeks , the implants had returned to their initial stability values. Implants with pISQ values greater than 69 exhibited decreased stability during the first 4 weeks after which they maintained consistent stability. Similarly in 1999 Friberg et al stated that the stability of implants placed in softer bone would catch up over time to implants placed in denser bone[21]. Balshi et al and Olsson et al came to the conclusion that implants with high primary stability lost part of their stability during healing whereas implants with low primary stability have a tendency to increase their stability.[6]

Meredith 1996 et al and Friberg et al 1999 has also proposed that the initial implant stability decreases as a result of bone compression caused by mechanical bone relaxation, biological change during the primary bone recovery stage and initiation of marginal bone resorption[34,21]. Glauser et al in 2001 performed RFA for 6 months after implantation of Ti unite and machined surface which showed a decreasing pattern for first 3 weeks and then an increasing pattern thereafter[25].

Antonin Simuneck et al reported that a significant increase in stability was recorded for the implants with low primary stability (PISQ<68), whereas the implant with high primary stability (PISQ >72) lost some of the stability over time. On the basis of linear regression analysis , the change in ISQ attains a value of zero at a primary ISQ of 69.2.[40] Typically implant stability is anticipated to decrease during the early weeks of healing. This is followed by an increase in stability .This is related to the biologic reaction of the bone to surgical trauma. During the initial bone remodeling phase , bone and necrotic material are resorbed by osteoclatic activity .It is reflected by a reduction in the ISQ value. This process is

followed by new bone apposition initated by osteobalastic activity i.e adaptive bone remodeling around the implant .There is a lack of agreement among investigators regarding the exact timing of greatest decrease in post insertion stability of an implant. The recorded data range between the 3 rd and 8th weeks following implant placement.[37,39,40.41]

Several factors may explain the drop of the ISQ during the first 3 – 6 months. The lateral compression exerted by the tapered implant on the osteotomy walls which allows high primary stability may produce micro fracture of the cortial bone or elastic adaptation of the trabecular bone which may result in the decrease of the ISQ. The remodeling process of bone resorption and bone deposition that takes place during the early phase of osseo integration may reduce the stiffness of the implant bone system. Conversely , the mineralization that occurs on the cortical bone as a part of the healing reaction to surgical wounding and bone maturation around the implants explain the increase in ISQ values from the 3 or 6 months to 12 months.

ISQ variation over a 1 year period as observed in the present investigation seems to match the timing of bone formation and maturation described by Roberts. According to Roberts, in Humans, the initial bone resorption and formation last about 4 months and 8 more months are necessary for complete bone maturation. The absolute RFA values are not completely dependant on the quality of osseointegration .There are three important factors that can directly influence RFA : i) the stiffness of the implant bone interface ii) stiffness of the bone itself and iii) stiffness of the implant components. Consequently , the clinically measurable characterisitic of implant stability can be compared in the follow up of each individual implant. But caution should be exerted in comparing these values among different implants , either in the same patient or inter individually.

Another important observation in the present study is that there is no statistically significant difference between the implant stability quotient (ISQ) values of Al Oxide blasted / acid etched surface (Group A) and Resorbable blast medium (RBM) treated (Group B) at different time intervals .(p value ranging from 0.4 to 0.7). This implies that both the surface treatments researched in this study have the same effect on longterm implant stability. Similar results are obtained by Sun – Jong Kim et al in his study who concluded that the three groups (machined ,SLA and anodized) did not show any significant difference in primary stability in experimental dogs[41]. Schincaglia et al concluded that there is no difference in ISQ values of machined and TiO surface coated implants over a period of one year [38]. Similar results were obtained by Karen fung et al over a 3 year split mouth clinical study on anodized and machined titanium implant surfaces[22]. However Jan Gottolow et al in his animal study concluded that SLA surfaces had more bone – implant contact and showed high removal torque values than Oxidised surfaces after 6 weeks of healing[29]. Jeffcoat et al found hydroxyapatite coated threaded implants to be more successful than HA coated cylinders and machined titanium implants over a period of 5 years clinically. [33]

In the present study, the surfaces tested were Al Oxide blasted / acid etched surface (Group A) and Resorbable blast medium (RBM) (Calcium phosphate treated surface) treated (Group B) . Both the surfaces showed similar primary and long term stability over a period of one year. SLA surfaces have been extensively studied and proven to be effective in enhancing implant stability when compared with machined and oxidized surfaces. SLA treatment – a combination of blasting and acid treatment is performed by sandblasting the implant with 25 – 50 μm Al_2O_3 particles and then etching with HCl / H_2SO_4 mixed solution . Esposito et al observed an increase in alkaline phosphaase activity, DNA absorption in 3H

chimicin's and collagenase by biochemically testing the condition of cultured cells in the SLA treated titanium phase.[18,19] Ganeles et al in 2008 reportd that even in poor bone quality , SLA active surface were safe and predictable when used in immediate and early loading procedures. The survival rate was comparable with that of conventional loading. In SLA treated implants , there was a significant difference in bone density between cancellous and compact bone. This result suggests that there is a significant difference in bone response according to bone quality in textured surface.

Implants with rough surfaces show a high success rate and an excellent clinical outcome when used in poor quality bone. Wennerberg et al stated that the bone to implat contact ration was higher in titanium implants with surface roughness of about 1.4 μm than in smoother implants (Sa =0.7 – 1.2 μm) or rougher implants (2.2 μm).[47]

However the concerns regarding the leaching of elemental Al ions in the peri implant bone tissue in case of SLA treated implants led to other surface treatments with biocompatible materials like Hydroxyapatite and calciumphosphate. Calcium phosphate is used as the resorbable blast medium in the test group. It is claimed that RBM treated surfaces are osteoconductive and there is an increase in Ca ion concentration in the peri implant host tissue leading to improved osteogenesis , bone maturation and differentiation.RBM treatment creates an extremely clean implant surface that does not inhibit gathering of osteoblast precursor cells. This can however be verified only at the cellular level. As far as clinical implant stability is concerned , both groups of implants with different surface treatments showed similar results which were clinically acceptable. All the implants were successfully integrated as revealed by the ISQ values and function well to support the prosthesis. Evaluation of other parameters like peri implant soft tissue health , radiographic bone levels, patient perception etc., might reveal

differences if any among these two groups of implants and the clinician can make his choice based on those factors given the fact that both types of implant achieve good primary and longtem stability. Future research in this direction including assessment of peri implant soft tissue health , microflora and histomorphometric analysis is warranted .

Summary and Conclusion

The present clinical study was conducted to determine the difference in the primary and progressive stability if any, between two types of root form endosseous implants with two distinct implant surfaces namely Acid etched surface/ Al Oxide blasted surface and Restorable blast media (RBM) (Calcium phosphate) treated surface when loaded immediately with a full arch fixed prosthesis. The study was designed to be a split mouth prospective clinical trial in which each patient received both the types of implants investigated in either of the two quadrants of the mandible. The null hypothesis was that there is no difference in the clinical stability of the two implant surfaces over a period of one year. A total of 5 Completely edentulous patients who fulfilled the inclusion and exclusion criteria were selected and written consent was obtained. A total of 30 implants (n = 15 for each group) were placed. The Alumina oxide blasted / acid etched surface (TOUAREG-S) is taken as the control (Group A) and the Resorbable blast media (RBM) surface (TOUAREG-OS) is taken as the test group(Group B) . All the implants were functionally loaded immediately with a fixed screw retained hybrid denture opposing the maxillary conventional complete denture.

The clinical implant stability of all the 30 implants were measured individually at different intervals - at the time of insertion, 1 month, 3 months, 6 months & 12 months after insertion. The primary implant stability was measured using the calibrated torque wrench (Insertion torque Value – ITV) and Resonance frequency Analysis (RFA). The progressive stability at different time intervals were measured using RFA and the Implant Stability Quotient (ISQ) values are recorded. The results were tabulated and subjected to statistical analysis.

The findings of the present study show that the insertion torque values (ITV) for both Al Oxide blasted / acid etched surface(group A) and Resorbable blast medium (RBM) (Calcium phosphate) treated surface (group B) were found to be in the range of >35 to >70 Ncm.

The mean Implant Stability Quotient (ISQ) value for Al Oxide blasted / acid etched surface(group A) was found to be 68.27, 54.26, 69.80 , 75.47 and 75.80 respectively and that of Resorbable blast medium (RBM) (Calcium phosphate) treated surface (group B) was found to be 70.67, 55.50 69.56 76.83 and 77.5 respectively when measured at the time of insertion, 1 month, 3 months, 6 months & 12 months after insertion. There is a statistically significant difference in stability for both the groups when compared individually among themselves over a period of one year ($p = 0.000$) and there is no statistically significant difference in stability between Al Oxide blasted / acid etched surface implants(group A) and Resorbable blast medium (RBM) (Calcium phosphate) treated surface (group B) at different time intervals - at the time of insertion, 1 month, 3 months, 6 months & 12 months after insertion. ($p =0.54$, 0.41, 0.96, 0.67 and 0.59 respectively).

Conclusion

The following conclusions were drawn from the present clinical study conducted for the comparative evaluation of primary and progressive stability of two different types of implants with different surface treatments namely i) Al Oxide blasted / acid etched surface & ii) Resorbable blast medium (RBM) (Calcium phosphate) treated surface loaded immediately with a fixed full arch prosthesis.

1. The insertion torque values (ITV) for both Al Oxide blasted / acid etched surface(group A) and Resorbable blast medium (RBM) (Calcium phosphate) treated surface (group B) were found to be in the range of >35 to >70 Ncm.
2. The mean Implant Stability Quotient (ISQ) value for Al Oxide blasted / acid etched surface(group A) was found to be 68.27 and that of Resorbable blast medium (RBM) (Calcium phosphate) treated surface (group B) was found to be 70.67 immediately after placement (primary stability).
3. The mean Implant Stability Quotient (ISQ) value for Al Oxide blasted / acid etched surface(group A) was found to be 54.26 and that of Resorbable blast medium (RBM) (Calcium phosphate) treated surface (group B) was found to be 55.50 at one month after placement .
4. The mean Implant Stability Quotient (ISQ) value for Al Oxide blasted / acid etched surface(group A) was found to be 69.80 and that of Resorbable blast medium (RBM) (Calcium phosphate) treated surface (group B) was found to be 69.56 at three months after placement.

5. The mean Implant Stability Quotient (ISQ) value for Al Oxide blasted / acid etched surface(group A) was found to be 75.47 and that of Resorbable blast medium (RBM) (Calcium phosphate) treated surface (group B) was found to be 76.83 at six months after placement.
6. The mean Implant Stability Quotient (ISQ) value for Al Oxide blasted / acid etched surface(group A) was found to be 75.80 and that of Resorbable blast medium (RBM) (Calcium phosphate) treated surface (group B) was found to be 77.5 at twelve months after placement.
7. There is a statistically significant difference in stability among the Al Oxide blasted / acid etched surface implants(group A) at different time intervals - at the time of insertion, 1 month, 3 months, 6 months & 12 months after insertion. (p =0.000).
8. There is a statistically significant difference in stability among the Resorbable blast medium (RBM) (Calcium phosphate) treated surface (group B) at different time intervals - at the time of insertion, 1 month, 3 months, 6 months & 12 months after insertion. (p =0.000).
9. There is no statistically significant difference in stability between Al Oxide blasted / acid etched surface implants(group A) and Resorbable blast medium (RBM) (Calcium phosphate) treated surface (group B) at different time intervals - at the time of insertion, 1 month, 3 months, 6 months & 12 months after insertion. (p =0.54 , 0.41, 0.96, 0.67 and 0.59 respectively).

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Abstract

Background :

Implant surface treatments influence the primary and longterm clinical stability of implants and their loading protocols. Numerous in vitro and animal studies have researched the influence of surface treatments on osseointegration at histological level. However Prospective clinical trials to study this aspect are relatively few. Hence, the present clinical study was conducted to determine the difference in the primary and progressive stability if any, between two types of root form endosseous implants with two distinct implant surfaces.

Materials and method :

Two different implant surfaces namely Acid etched surface/ Al Oxide blasted surface (Group A) and Resorbable blast medium (RBM) (Calcium phosphate) (Group B) treated surface were compared after loading immediately with a full arch fixed prosthesis. Five completely edentulous patients received a total of 30 implants (n =15 for each group) in the mandible and rehabilitated immediately with a fixed screw retained hybrid denture. The clinical implant stability of all the 30 implants were measured individually at different time intervals - at the time of insertion, 1 month, 3 months, 6 months & 12 months after insertion. The primary implant stability was measured using the calibrated torque wrench (Insertion torque Value – ITV) and Resonance frequency Analysis (RFA). The progressive stability at different time intervals were measured using RFA and the Implant Stability Quotient (ISQ) values are recorded. The results were tabulated and subjected to statistical analysis.

Results :

The findings of the present study show that the insertion torque values (ITV) for both Al Oxide blasted / acid etched surface(group A) and Resorbable blast medium (RBM) (Calcium phosphate) treated surface (group B) were found to be in the range of >35 to >70 Ncm. The mean Implant Stability Quotient (ISQ) value for Al Oxide blasted / acid etched surface (group A) was found to be 68.27, 54.26, 69.80 , 75.47 and 75.80 respectively and that of Resorbable blast medium (RBM) (Calcium phosphate) treated surface (group B) was found to be 70.67, 55.50, 69.56, 76.83 and 77.5 respectively when measured at the time of insertion, 1 month, 3 months, 6 months & 12 months after insertion. There is a statistically significant difference in stability for both the groups when compared individually among themselves over a period of one year ($p = 0.000$) and there is no statistically significant difference in stability between Al Oxide blasted / acid etched surface implants(group A) and Resorbable blast medium (RBM) (Calcium phosphate) treated surface (group B) at different time intervals - at the time of insertion, 1 month, 3 months, 6 months & 12 months after insertion. ($p =0.54 ,0.41,0.96,0.67$ and 0.59 respectively).

Conclusion :

Within the limitations of this study , there is no statistically significant difference in stability between Al Oxide blasted / acid etched surface implants and Resorbable blast medium treated surface at different time intervals. However, there is a statistically significant increase in stability over time for both the groups of implants when assessed individually.

Patient Consent Form

(Regional Language)

ஆராய்ச்சி ஒப்புதல் படிவம்

செயற்கை வேர் (இம்ப்ளான்ட்) பதியம் செய்து நிரந்தர செயற்கை பல் செட் பொருத்தும் முறைகள் குறித்த ஒப்பீட்டு ஆய்வு,

பெயர்: தேதி:

வயது: உள்/புறநோயாளி எண்

பாலினம்: ஆராய்ச்சி சேர்க்கை எண்

என்னுடைய சுய நினைவுடனும் மற்றும் முழு சுதந்திரத்துடனும் இந்த மருத்துவ ஆராய்ச்சியில் சேர்ந்துகொள்ள ஒப்புதல் அளிக்கிறேன்.

கீழ்காணும் நிபந்தனைகளுக்கு நான் ஒப்புக்கொள்கிறேன்.

இந்த சிகிச்சையின் போது என் கீழ்தாடையில் செயற்கை வேர் (இம்ப்ளான்ட்) பொருத்தப்பட்டு அதன் மீது நிரந்திர பல்செட் பெருத்தபடும் என்பதை அறிகிறேன்.

புற நோயாளிப்பிரிவில் செய்யப்படும் சிகிச்சையின் போது என் தாடை, உதடு, கன்னம் ஆகியவை தற்காலியமாக மறத்துபோவதற்காக ஊசி மருந்துகள் அளிக்கப்படும் (Local anesthesia) என்பதையும், தாடை எலும்பில் சிறிய துளைகள் இடப்பட்டு அவற்றில் டைட்டனியம் (Titanium) உலோகத்தினால் செய்யப்பட்ட செயற்கை வேர்கள் பொருத்தப்பட்டு, பின்பு தையல் இடப்படும் என்பதையும் அறிவேன். இச்சிச்சையின் போது நீண்ட நாட்கள் உதடுகள் மறத்துப்போகவும், (Paraesthesia) தாடை எலும்பு முறிவு, ஒவ்வாமை, குறுகியகால இரத்தப்போக்கு, ஆகியவை ஏற்பட வாய்ப்பு உண்டு என்பதையும் அறிவேன். சில சமயங்களில் பொருத்தப்பட்ட இம்ப்ளான்ட் எலும்புடன் இணையாமல் கழன்றும் வரலாம் என்பதையும் அறிவேன்.

எனது உடல்நிலை பாதிக்கப்பட்டலோ அல்லது எதிர்பாராத வழக்கத்திற்கு மாறான நோய்க்குறிகள் தென்பட்டாலோ அதனை உடனடியாக பல்மருத்துவரிடம் தெரிவிக்க சம்மதிக்கிறேன்.

எனது மருத்துவ குறிப்பேடுகளை இந்த ஆராய்ச்சியில் பயன்படுத்திக்கொள்ள சம்மதிக்கிறேன். இந்த ஆராய்ச்சி மையமும், ஆராய்ச்சியாளரும் என்னுடைய விவரங்கள் அனைத்தையும் இரகசியமாக வைப்பதாக அறிகிறேன்.

(P.T.O)

மேலும் இந்த ஆய்ச்சிகளுக்கு தேவைப்படும் இரத்தப்பரிசோதனை, எக்ஸ்-ரே மற்றும் புகைப்படங்கள் எடுக்க ஆராய்ச்சியாளருக்கு அனுமதி அளிக்கிறேன்.

இம்ப்ளாண்ட் பொருத்தப்பட்டு பின்பு புகைபிடித்தாலோ, வாய், ஈறு மற்றும் பல்செட்டை சுத்தமாக பராமரிக்காமல் இருந்தாலோ சிகிச்சையின் விளைவுகள் பாதிக்கப்படலாம் என்பதை அறிவேன்.

.....	.....	.....
நோயாளியின் பெயர்	கையொப்பம்	தேதி

.....	.....	.....
ஆராய்ச்சியாளரின் பெயர்	கையொப்பம்	தேதி